Pharmaceuticals and Medical Devices Safety Information

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Executive Summary

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Full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 282 will be upcoming soon. The contents of this month's PMDSI are outlined below.

1. Revision of Contraindications for the Use of Coronary Stent

Coronary stent, a medical device percutaneously placed in coronary artery, improves regional myocardial blood flow by dilating stenotic artery. Previously, the use of coronary stent has been contraindicated in acute myocardial infarction patients or patients with lesions located in the unprotected left main coronary artery, etc. However, since those off-label uses are well-recognized in real clinical settings, MHLW conducted a hearing from the Japanese Circulation Society, and PMDA reviewed about this matter. Accordingly, the contraindications for coronary stent were revised. The details of the revision and the importance of cooperation between cardiovascular internal physicians and cardiac surgeons when using coronary stents are described in section 1 of the Full text document.

2. Revision of Contraindications for the Use of Intraocular Lens

Intraocular lens (IOL) is a medical device to be inserted in the posterior or anterior chamber of the eye after removing crystalline lens to improve visual acuity for cataract patients. Previously, the use of IOL has been contraindicated in children or in patients with uncontrolled glaucoma, proliferative diabetic retinopathy, or active uveitis, etc. However, the Japanese Ophthalmological Society and other organizations submitted a petition calling for a review of the contraindications based on the experience and results of IOL use in clinical settings. In view of the above, PMDA conducted a review and the contraindications for IOL were revised. The details are described in section 2 of the Full text document.

3. Important Safety Information

This section presents the contents of the revisions and case summaries that served as the basis for these revisions to important adverse reactions included under the "Precautions" section of package inserts of drugs that have been revised in accordance with the Notification dated July 5, 2011.

1. Oxaliplatin
2. Recombinant Adsorbed Hepatitis B Vaccine (yeast-derived) (Bimmugen)
3. Sunitinib Malate
4. Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed)
5. Varenicline Tartrate
6. Lenalidomide Hydrate

4. Revision of Precautions (No. 228)

Revisions of Precautions for the following pharmaceuticals are included in Section 4 of the Full text document.

Pioglitazone Hydrochloride, Pioglitazone Hydrochloride/Glimepiride, Pioglitazone Hydrochloride/Metformin Hydrochloride, Ergotamine Tartrate/Anhydrous Caffeine/Isopropylantipyrine, Gabapentin, Terbutaline Sulfate, Bevacizumab (Genetical Recombination), Fexofenadine Hydrochloride, Recombinant Adsorbed Hepatitis B Vaccine (yeast-derived) (HEPTAVAX), Tocilizumab (Genetical Recombination),

5. List of Products Subject to Early Post-marketing Phase Vigilance

A list of products subject to Early Post-marketing Phase Vigilance as of August 1, 2011 is included in Section 5 of the Full text document.

PMDSI is also available on the Pharmaceuticals and Medical Devices Agency website (http://www.pmda.go.jp/english/index.html) and on the MHLW website (http://www.mhlw.go.jp/, Japanese only).